Based on U.S. claims data, we assigned doctors IDs based on the physician who treated the enrollee for the longest period of time after eliminating any emergency room, laboratory, and radiology services. Physician prescribing patterns were then calculated from prescription drug records. Patients were grouped as generic SSRIs, non-generic SSRIs, and SNRIs. RESULTS: We identified the doctors' prescribing pattern with the percentage of time they prescribed SSRIs, non-generic SSRIs and SNRIs. We showed that patients were more likely to be prescribed generic SSRIs relative to non-generic SSRIs if doctors' prescribing patterns favored generic prescription (p = 0.000). Similarly, patients were less likely to be in the SSRIs group if doctors' prescribing patterns favored SNRI prescription (p = 0.000). CONCLUSIONS: Doctors' prescribing patterns are important factors for decisions on treatment. Any outcomes models (compliance, or treatment effect on health care utilization and cost) should control for these patterns.

PMH92

TIME SERIES ANALYSIS TO EXAMINE THE EFFECT OF GUIDELINES

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OBJECTIVES: Application of a segmented times series model to measure the effect of guidelines on outcomes measures. METHODS: To isolate the effect of guidelines, we need to control for three different factors: 1) Baseline differences between the two groups, 2) Step-wise differences at the intervention point, and 3) Trend differences after the intervention. The segmented times series model was combined with the propensity score matching technique. The segmented time series model contained two predictor variables: the binary intervention variable and an interval coding for time. The kitchen sink approach was used for propensity score matching and the segmented time series model controlled for the confounding influence of any underlying trend. The final model ensured that any estimated change in the mean level of the series after intervention was not simply due to the series' trend. RESULTS: Using U.S. claims data, we analyzed the effect of the American Psychiatric Association's consensus statement on glucose monitoring for patients on atypical antipsychotic drugs. Glucose screening rose 1% per quarter among antipsychotic-treated patients before release of the guidelines, compared to 0.5% per quarter after (P = 0.005 for trend). Monitoring rates were 16.07% before release of the guidelines and 18.76% after (P < 0.001). CONCLUSIONS: The segmented time series model can provide a clear picture about both trend and intervention effect when analyzing the effects of guidelines.

PMH93

AGREEMENT BETWEEN PATIENTS WITH MILD DEMENTIA AND CAREGIVERS ON THE PROMIS CAT MEASURE OF PERCEIVED COGNITIVE FUNCTION

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OBJECTIVES: The PROMIS measure of Perceived Cognitive Function has gone through multiple cycles of development and validation testing, but has not been extensively tested in clinical settings, particularly among patients being treated for neurological conditions and/or cognitive deficits. We sought to do an initial examination of the extent to which patients being treated for mild dementia and their caregivers would agree in their assessment of patient cognitive function using the PROMIS PCF measure. **METHODS**: A total of 14 consecutive patients being seen in the Neurology outpatient clinic at Henry Ford Hospital for a diagnosis of dementia, as well as one adult caregiver per patient, were invited to complete the PROMIS Perceived Cognitive Function CAT measure in reference to the patient's current level of cognitive function. Several analyses of agreement between caregiver and patient reports were conducted. **RESULTS**: All patients and all caregivers were able to successfully complete the PROMIS PCF measure. There was no significant difference between patients and caregivers in either mean raw score, mean T-score, or standard error for the measure. The score ranges for caregivers and patients were quite comparable. The Pearson correlation coefficients for association between patient and caregiver responses were .246 and .286 for raw score and t-score, respectively (both n.s.). **CONCLUSIONS:** The lack of significant difference between patients and caregivers on mean response suggests possible validity of the PCF measure for group-level analyses, but the relatively low correlations between patient and caregiver suggest caution about use of the measure at the individual patient level. The next step of analysis will involve comparison of patient PCF scores to scores on objective measures of cognitive function.

MUSCULAR-SKELETAL DISORDERS – Clinical Outcomes Studies

PMS1

ASSESSMENT OF COMORBIDITIES IN PATIENTS WITH RHEUMATOID ARTHRITIS (RA)—FINDINGS FROM A RETROSPECTIVE CLAIMS DATABASE ANALYSIS USING A PRE-PROGRAMMED DATA ANALYSIS TOOL

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OBJECTIVES: RA is a systemic disease resulting in comorbidities that affect quality of life, prognosis and outcomes. Comorbid illnesses can impact treatment, medical costs, disability and risk of mortality. Rheumatoid Arthritis Outcomes Analyzer, a validated claims data analysis tool with a user-friendly interface was used to characterize comorbidities in patients with RA. **METHODS:** The study included patients age 18 or older with at least 2 diagnoses of RA (ICD-9 CM 714.0X) ≥ 2 months apart between January 2005 and December 2007 from the HealthCore Integrated Research Database[SM]. Patients must have received ≥ one traditional (non-biologic) or biologic DMARD medication with RA diagnoses at least two months apart. All medical and pharmacy claims were entered into the final dataset. **RESULTS:** A total of 25,856 RA patients entered into the analysis (mean age = 56; 74.8% female). The overall mean Charlson Comorbidity Index (CCI) was 2.00 (SD = 1.63) and was higher for males (mean = 2.18; SD = 1.85) than females (mean = 1.94; SD = 1.55). In the 18 to 44 age group, females tended to have a higher CCI (mean = 1.38; SD = 0.91) than males (mean = 1.30; SD = 0.81). This trend reverses in older patients where the mean CCI in males in the 45 to 64 and ≥ 65 age groups is 1.90 (SD = 1.50) and 3.31 (SD = 2.39) respectively versus 1.76 (SD = 1.29) and 2.80 (SD = 2.07) in females. The most frequent comorbid conditions for all patients were; chronic pulmonary disease, diabetes, cerebrovascular disease, tumor, congestive heart failure, peripheral vascular disease and renal disease. **CONCLUSIONS:** This analysis explores and differentiates the CCI by gender and age group in patients with RA using a validated claims data analysis tool. Further study will examine the relationship between comorbidity and health-related and cost outcomes.

PMS2

ESTIMATING HEALTH-RELATED UTILITY FROM CLINICALLY ASSESSED DISEASE SEVERITY IN ANKYLOSING SPONDYLITIS

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OBJECTIVES: We sought to conduct a statistical mapping analysis between a standard investigator assessment of disease severity in ankylosing spondylitis (AS) and domain responses in a standard index of health utility; and secondly, to implement the above mapping in an optimised algorithm to estimate utility. **METHODS:** Multinomial logistic regression was used to estimate response probabilities to each domain of the EQ5D from the Bath Ankylosing Spondylitis Metrology Index (BASMI) among patients enrolled into an RCT studying the use of either etanercept infusion vs. oral sulphasalazine (ASCEND). Other covariates tested were gender, age, co-morbidity, AS duration, DMARD history, and concurrent medications. Predicted EQ5Dindex was estimated by Monte Carlo bootstrap simulation. The predictive ability of the response mapping was assessed by comparing estimated and directly measured utility derived from the UK tariff. **RESULTS:** Evaluable data were available for 566 predominantly white (87%) patients, 74% of whom male, with a mean baseline age of 41 years (sd 12) and median AS duration 4 years (IQR 1 to 11). Average BASMIlinear was 4.1 (sd 1.8) whilst median observed EQ5D utility was 0.587 (IQR 0.193 to 0.691). The linear definition of the BASMI was optimal in an algorithm that also adjusted for gender, AS duration, number of co-morbid body systems, number of historic DMARDs, number of current non-DMARD drugs, and current NSAID use. The mean utility predicted by the optimized algorithm was 0.552 (sd 0.101) and 0.559 (sd 0.295) by estimation directly from EQ5D responses (p = 0.238). The mean squared error between the actual and predicted utilities was 0.076 (sd 0.111). Adjusted utility was defined by −0.044*BASMIlinear+0.715, with an R^2 of 0.62. **CONCLUSIONS:** In this study, response mapping of AS disease activity to the EQ5Dindex produced reliable estimates of preference-based health-related utility. Future analysis will compare the relative ability of patient-reported, AS-specific, functional assessment measures in predicting health-related utility.

PMS3

A BAYESIAN ANALYSIS OF BISPHOSPHONATE EFFICACY FOR THE TREATMENT OF POSTMENOPAUSAL OSTEOPOROSIS

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OBJECTIVES: The aim of this study was to evaluate the effectiveness of five bisphosphonates approved for the treatment of postmenopausal osteoporosis. **METHODS:** Randomized placebo controlled studies describing the occurrence of clinical vertebral (CVF), morphometric vertebral (MVF) and nonvertebral fractures (NVF) were identified by searching the Cochrane Database, International Pharmaceutical Abstracts and Ovid Medline. Studies were eligible if patients had suffered a fracture at entry or had a bone mineral density at least 2 SD below the mean value for young adult females. WinBUGS was used to conduct the analysis, which permitted combining direct and indirect evidence to rank order the treatments. **RESULTS:** A total of 39 studies were identified. All five bisphosphonates were found to reduce the relative risk of new fractures in women with postmenopausal osteoporosis. For CVF, all ORs for treatments compared to placebo were statistically significant, suggesting that treatment with any agent is better than none. Zoledronate was the most effective treatment (OR = 0.22, 95%CRI:0.13–0.36), followed by both alendronate (OR = 0.48, 95%CRI:0.30–0.76) and ibandronate (OR = 0.51, 95%CRI:0.34–0.77) as these could not be differentiated statistically (no data were available for etidronate and risedronate). For MVF also, all ORs for treatments compared to placebo were statistically significant. Zoledronate (OR = 0.28, 95%CRI:0.22–0.35) and etidronate (OR = 0.29, 95%CRI:0.17–0.48) were both most effective, followed by alendronate (OR = 0.52, 95%CRI:0.42–0.64), risedronate (OR = 0.56, 95% 0.45–0.70) and ibandronate (OR = 0.67, 95% 0.54–0.83); The last three could not be differentiated. For NVF the ORs for zoledronate (OR = 0.70, 95%CRI:0.60–0.80), risedronate (OR = 0.71,

95%CRI:0.58–0.88) and alendronate (OR = 0.80, 95%CRI:0.70–0.91) compared to placebo were statistically significant, while those for ibandronate (OR = 0.91, 95%CRI:0.41–2.09) and etidronate (OR = 0.95, 95%CRI:0.44–2.12) were not. When the treatments were compared directly to each other, none of the treatments were statistically more effective than others. **CONCLUSIONS:** Overall, zoledronate appeared to be most effective at reducing fractures in women with postmenopausal osteoporosis.

MUSCULAR-SKELETAL DISORDERS – Cost Studies

PMS4

CHARACTERIZING UNCERTAINTY IN EARLY-DEVELOPMENT BUDGETARY IMPACT MODELS: A CASE STUDY OF DENOSUMAB

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OBJECTIVES: Budgetary impact modeling often occurs early, amidst uncertainty surrounding the eligible patient population or the final price of a new intervention. Uncertainty can be characterized using per-member per-month (PMPM) iso-curves that graphically depict the net budgetary impact at different prices and population sizes. The objective of this study is to examine the use of PMPM budgetary impact (PMPMBI) iso-curves to represent budgetary uncertainty for products prior to regulatory approval, using denosumab as an example. **METHODS:** A 3-year Markov cohort budgetary impact model (BIM) was developed for denosumab in the treatment of postmenopausal osteoporosis in a hypothetical US managed care plan. The model incorporates current market shares and persistence on osteoporosis treatments, and calculates the net impact of adding denosumab to the health plan. Direct costs include drug costs and medical cost offsets due to reductions in osteoporotic fractures. The model was used to construct PMPMBI iso-curves for each of the 3 model years by systematically varying the price of denosumab and the number of patients receiving treatment while holding all other parameters constant. **RESULTS:** In year 1, the PMPMBI iso-curves ranged from $–0.06 to $0.08 using the lower and upper limits of price and population size assumptions. The lower iso-curves occur at lower prices and/or population sizes and vice versa. Budget impact is insensitive to the size of the patient population when the price of denosumab is equal to the weighted average price of all other interventions. **CONCLUSIONS:** Iso-curves can be used to concisely report BIM results over a wide range of price and population size assumptions. The budgetary impact of denosumab can easily be interpolated once price and population size are known, allowing decision-makers to estimate PMPM costs soon after product approval.

PMS5

MEDICAL COSTS FOLLOWED BY FALLS/SLIPS AT A TEACHING HOSPITAL IN JAPAN

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OBJECTIVES: Medical costs followed by incidents within hospitals are not linked with primary diseases and might be paid by hospitals. In that manner, it is very important for hospital managers to recognize the actual situation of medical costs for incidents. Cases injured with over the level two and their medical costs for a year are explored. **METHODS:** There are 2,866 incident reports in 2007 collected at Saint Mary's Hospital in Kurume-City, Fukuoka, Japan. Their reports include 734 cases for Falls/Slips and 2,132 cases for others. The cases for Falls/Slips are classified 474 with level 1, 320 with level 2, and 136 with level 3a, and 14 with level 3b, respectively. Of the 14 cases with level 3a included three femoral neck fractures and femoral trochanteric fractures each, and one femoral shaft fracture, facial fracture, clavicle fracture, shoulder fracture, upper extremity fracture, lower extremity fracture, thoracic vertebral fracture, and traumatic subarachnoid hemorrhage,each. **RESULTS:** According to the injury level, average medical costs are 88 dollars (level 2, 59 cases), 94 dollars (level 3a, 86 cases), and 12,330 dollars (level 3b, 14 cases). Medical costs with level 2 and 3a are directly calculated from the medical fee schedule under the social insurance system. By contrast, medical costs with level 3b are alternated by the average medical fee of the same diseases at the hospital, because we can not separate medical costs for injury by incidents and for primary diseases. For example, averaged medical cost for femoral neck fracture is 18,400 dollars by calculating 182 cases with same diseases were treated at our hospital. **CONCLUSIONS:** Total amount of medical costs for Falls/Slips is about 19 million dollars at our hospital for the year of 2007. Therefore, Hospital administrators have to take appropriate measures to prevent patients from Falls/Slips and save money, because this amount is not overlooked.

PMS6

COMPARISON OF COST OF ALLOPURINOL VS FEBUXOSTAT AS A FIRST LINE TREATMENT FOR GOUT

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OBJECTIVES: The objective of this study was to build a decision analytic model to estimate the cost and effectiveness of allopurinol 300 mg/d and febuxostat 80 mg/d as a first line treatment for gout patients based on available clinical and cost data. **METHODS:** We built a decision analytic model as a decision tree using TreeAge Pro 2009, in which allopurinol was compared to febuxostat as a first line treatment for gout. The model examined two time horizons: 1–8 weeks and 9–52 weeks. Treatment success from week 1–8 was defined as no case of gout flare. If a gout flare occurred within week 1–8 there was an equal chance of continuing on treatment or switching to the alternative treatment strategy during weeks 9–52. During weeks 9–52 treatment failure occurred with report of a gout flare. Treatment failure due to gout flare was assumed to result in an additional physician visit. Costs of adverse events (musculoskeletal, joint-related signs and symptoms, liver function test abnormalities) from treatment were accounted for and assumed to result in a doctor visit. Data used to construct the economic model were derived from published clinical trials as well as available sources of physician and drug costs. Sensitivity analyses were preformed to assess the impact of variations on all model inputs. **RESULTS:** Total cost of allopurinol as a first line treatment for gout was $1125 compared to $7737 for febuxostat as a first line treatment for gout. Sensitivity analyses indicate the model is most sensitive to pill price. All else equal, a monthly supply of febuxostat would need to cost less then $3 to be as cost-effective as allopurinol. **CONCLUSIONS:** Allopurinol was $6612 less as a first line treatment compared to febuxostat and therefore the cost effective treatment and as such should remain a first line treatment.

PMS7

COST ANALYSIS OF RECENTLY APPROVED AND OLDER ANTI-TNF BIOLOGIC AGENTS USED IN RHEUMATOID ARTHRITIS

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OBJECTIVES: Historical comparative cost analyses have included adalimumab (ADA), etanercept (ETA), and infliximab (IFX). More recently, certolizumab pegol (CTP) and golimumab (GLM) have been FDA-approved for use in RA. The objective of this analysis was to estimate and compare annual drug and treatment costs of all anti-TNF agents approved for use in RA based on FDA-approved prescribing information. **METHODS:** A cost analysis was conducted using FDA-approved prescribing information to calculate cumulative dose and administration schedule over a 12-month time horizon. Wholesale acquisition costs were obtained from First Databank for December 2009, with annual costs computed using labeled dosing. ADA cost was based on 26 injections of 40 mg every other week. CTP cost was calculated based on 15 injections of 400 mg (weeks 0, 2, and 4 loading doses and 400 mg every 4 weeks maintenance dosing). ETA cost was based on 52 injections of 50 mg once weekly. GLM cost was based on 12 injections of 50 mg once monthly. IFX cost was calculated based on 100 mg vials for initial dosing of 3 mg/kg (75 kg patient) with dose increase to 5 mg/kg at 6 months (weeks 0, 2, and 6 loading doses with every 8 week maintenance infusions; infusion fee = $181.05 per infusion from 2009 CMS Physician Fee Schedule). Costs of adverse events and concomitant methotrexate were assumed equivalent across all agents. A sensitivity analysis was conducted to assess impact of average sales price (ASP) on results. **RESULTS:** Annual drug only costs were $19,812 (ADA), $21,940 (CTP), $20,190 (ETA), $19,824 (GLM), and $16,306 (IFX). Including administration fees for infusion, the annual treatment cost of IFX was $17,754. A sensitivity analysis using ASP + 6% yielded similar results. **CONCLUSIONS:** Annual treatment costs of anti-TNF agents, including newer agents, are comparable when used for RA patients according to label.

PMS8

HIGH-COST MEDICATIONS IN 10 COUNTRIES: A CROSS-SECTIONAL COMPARATIVE STUDY

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OBJECTIVES: To compare, between European and Latin American countries, the list prices of brands for the most expensive drugs in Colombia (Imatinib, Abacavir + Zidovudine + Lamivudine, Docetaxel, Etanercept, Filgrastim, Gemcitabine, Infliximab, Interferon Beta 1 A, Interferon Beta1 B, Leuprolide, Lopinavir + Ritonavir, Mycophenolate, Octreotide, Paclitaxel, Somatotropin and Temozolamide). **METHODS:** We searched for list prices of the 16 most expensive drugs, as charged to the Colombian state, from 21 manufacturers in 10 countries. In Europe: Belgium, Spain and the UK were analyzed, while in Latin America: Chile, Colombia, Ecuador, Paraguay, Peru and Uruguay were studied. For the data analysis, UK list prices were used as the standard. **RESULTS:** For comparison purposes, we selected 21 manufacturers offering these high-cost medications in the 10 countries analyzed, leading to a pool of 210 potential market prices. Out of them, 142 were obtained (we had the 21 for the UK). A total of 101 prices (71.1%) are higher than those in the UK. Average prices are 168.5% (SD0.99) of the UK price. The average for Latin American countries was 197.4% (SD1.13) of the UK price, and 118.6% (SD 0.31) for the European countries. The country with the highest average is Uruguay (294.7% UK price, SD0.95), followed by Colombia (278.5% UK price, SD1.13). The country with the lowest average is our standard, the UK (SD 100.0%), followed by Ecuador (105.1% UK price, SD 0.4). **CONCLUSIONS:** We found a significant difference between average prices in Europe and Latin America, the latter being much higher than the UK standards. If UK prices were used in Latin America, it would be possible to treat twice as many patients as are currently treated. In Colombia, based on the information available, around US$ 67 Million could be saved if UK prices were charged, assuming that purchases are made at list prices.